

REMARKS

Entry of the foregoing, reexamination, and further and favorable reconsideration of the subject application, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

I. Response to Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 3, 9, 11-16 and 25-31 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite. In particular, the Examiner has stated that the meaning of the phrases "microorganism fungus body" and "processed product of the microorganism fungus body" are unclear.

This rejection is respectfully traversed.

Microorganisms containing nitrile hydratase are described on page 7, line 25 to page 2, line 11 of the specification. In addition, the specification indicates that the microorganisms can be transformants (page 8, line 12 to page 9, line 1), such as the transformed bacterial strain (MT-10822) described in Example 1 of the specification. Furthermore, the microorganisms include transformants obtained by expressing a mutant nitrile hydratase that has been further improved in amide compound resistance, nitrile compound resistance and/or temperature resistance by displacing, deleting, canceling and/or inserting one or more amino acids of the enzyme with other amino acids by using DNA splicing techniques (page 9, lines 1-8). An example of a transformant expressing a mutant nitrile hydratase is provided in Example 2 of the specification.

The microorganism fungus body, in turn, can be prepared from the microorganism by any number of methods known in the fields of molecular biology, bioengineering and genetic engineering (page 9, lines 9-20).

The processed product of the microorganism fungus body is clearly defined in the specification as including an extract and a trituration product of the microorganism fungus body; a post-separated product obtained by separating and purifying a nitrile hydratase active fraction of the extract and the trituration product; and a fixed product obtained by fixing the microorganism fungus body, the extract, the trituration product or the post-separated product of the fungus body to an appropriate carrier (page 9, line 21 to page 10, line 5).

Therefore, the phrases "microorganism fungus body" and "processed product" would have been clear to a person of ordinary skill in the art. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

II. Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 3, 9, 11-16 and 25-31 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to comply with the written description requirement. According to the Examiner, a person of ordinary skill in the art would not have been able to identify without further testing what specific "microorganism fungus body" and "processed product of the microorganism fungus body" would have a nitrile hydratase that can be used in the claimed method. The Examiner has further stated that the bacterial nitrile hydratase disclosed in the specification does not sufficiently represent all nitrile hydratases.

This rejection is respectfully traversed.

As noted in the Appeal Brief filed in the present application on January 17, 2007, the position of the Examiner is contrary to established case law. The purpose of the written description requirement was originally provided to prevent applicants from adding material to a claim that was not originally described in the specification. The written description requirement was developed to require disclosure of information that provides the inventive advances in the technology, *i.e.*, such that any new inventive information is added to the field of art. The written description requirement does not serve to require a treatise on what is well known in the art. As the courts have repeatedly indicated, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Spectra Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ2d 1737 (Fed. Cir. 1987); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

This holding has more recently been applied to nucleic acid and amino acid sequences. For example, the Federal Circuit has held, "None of the cases to which the Board attributes the requirement of total DNA re-analysis, *i.e.*, *Regents v. Lilly*, *Fiers v. Revel*, *Amgen*, or *Enzo Biochem*, require a re-description of what was already known." *Capon v. Eshhar v. Dudas*, 418 F.3d 1349, 1357 (Fed. Cir. 2005). The necessity of reciting sequence

information for known proteins and genes was further addressed in *Falkner v. Inglis*, 79 USPQ2d 1001 (Fed. Cir. 2006). In *Falkner*, Falkner brought a motion challenging the Inglis application based upon written description for lacking description of any essential genes in poxvirus or describing the inactivation of such genes. In other words, Falkner challenged the specification for lacking written description of sequence information for genes in the poxvirus. The Federal Circuit, consistent with *Capon*, held:

[A] requirement that patentees recite known DNA structures, ... would serve no goal of the written description requirement. It would neither enforce the *quid pro quo* between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention.

...

Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly we hold that where, as in this case, accessible literature sources clearly provided ... their nucleotide sequences (here "essential genes")...

(*Falkner v. Inglis*, 79 USPQ2d at 1007-8).

The cases above side with Appellants' position that the claimed invention is fully supported by the specification. Appellants have provided exemplary nitrile hydratases that can be used in the invention and one of skill in the art can readily identify a large number of other nitrile hydratases using routine skill and knowledge. Appellants submit that the combination of the instant disclosure coupled with the knowledge of the skilled artisan sufficiently describes a genus of nitrile hydratases that may be used in the claimed method. As set forth in both *Capon* and *Falkner*, it is unnecessary to provide information that is already available to those of skill in the art. Furthermore, the recitation of a large number of nitrile hydratase sequences known in the art would serve no purposes under the written description requirement and would serve only to provide "unnecessary bulk to the specification." (*Falkner*, 79 USPQ2d at 1008).

Those of ordinary skill in the art were aware that nitrile hydratases are hydrolytic enzymes responsible for the sequential metabolism of nitriles in some bacteria and fungi and

were capable of utilizing aliphatic nitriles as the sole source of nitrogen and carbon. Thus, those of ordinary skill in the art would have recognized from reading the disclosure that the inventors had invented a method that accommodates the use of various nitrile hydratases, not just the exemplary enzymes set forth in the specification. Neither the claims , nor the specification need be more specific with regard to, for example, the structure of a nitrile hydratases useful in the present methods because the skilled artisan already has such information in his/her possession.

As noted previously, the novelty of the present method lies not in the particular nitrile hydratase used in the method, but instead lies in the combination of conditions identified by the Appellants as suitable for purifying an amide compound. The forced recitation of a specific hydratase in the claims is an unnecessary limitation on the claimed method. Further, the forced recitation of known sequences in the instant disclosure would only add unnecessary bulk to the specification. Accordingly, accessible literature sources clearly provided, as of the relevant date, information about nitrile hydratase from various sources including those deposited in accessible repositories.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this rejection.

III. Response to Claim Rejections Under 35 U.S.C. § 103

Claims 1, 3, 9, 11-16 and 25-31 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Oriel et al. (WO 99/55719) in view of Chen (J. Biol. Chem., 1967).

The Examiner has stated that since it was known in the art that activated charcoal is obtained by treating charcoal with acid, one of ordinary skill in the art would have recognized and predicted that nitrile compounds containing an unsaturated bond are stable in acidic conditions.

This rejection is respectfully traversed.

Applicants acknowledge that wood powder, for example, can be impregnated with zinc chloride-containing hydrochloric acid solution and baked to provide activated charcoal. However, the obtained activated charcoal is then washed with water to remove all but trace amounts of zinc chloride-containing hydrochloric acid. Therefore, the pH of the water solution suspended with the activated charcoal is almost neutral. As a result, even if Oriel et

al. showed that activated charcoal was used to purify acrylamide, one of ordinary skill in the art would not have recognized or predicted that nitrile compounds containing an unsaturated bond are stable in acidic conditions.

Furthermore, although Chen teaches a process step for removing lipid impurities contained within albumin (protein) samples by acid-charcoal treatment, the reference does not teach or suggest the present methods for removing protein by acid-charcoal treatment.

Oriel et al. teaches a process for purifying an acrylamide solution by treating with activated charcoal. However, in contrast to the present claims, Oriel et al. does not teach or suggest that the acrylamide solution, which is produced by contacting acrylonitrile with a nitrile hydratase (BR449), contains not only lipid but also protein impurities. Therefore, one of ordinary person in the art would not have combined the activated charcoal treatment process of Oriel et al. with the acid-activated charcoal treatment by Chen for removing lipid impurities contained within protein samples with any reasonable expectation of success.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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